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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/069,282 | 02/25/2002 | Shin-ichi Kaiho | KAIHO=3 | 1523 |

1444 7590 01/30/2004

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

| EXAMINER | |
|---|---|
| BADIO, BARBARA P | |
| ART UNIT | PAPER NUMBER |
| 1616 | |

DATE ~~MAILED~~: 01/30/2004
Restart

Please find below and/or attached an Office communication concerning this application or proceeding.

* wrong customer # was placed in system.

B. Shay
1/30/04

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| 10/069,282 | 02/25/2002 | Shin-ichi Kaiho | KAIHO=3 | 1523 |

144 7590 04/16/2003

RUBIN D. SILVERN
12 SULGRAVE ROAD
SCARSDALE, NY 10583

| EXAMINER | |
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| BADIO, BARBARA P | |

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DATE MAILED: 04/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/069,282 | KAIHO ET AL. | |
| | Examiner | Art Unit | |
| | Barbara P. Badio, Ph.D. | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *3,4,9,10,14-17,20,22 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-8,11-13,18,19,21 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3 & 6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

**First Office Action on the Merits**

***Election/Restrictions***

1. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(I) Compounds of formula (I) wherein $X^1$ is a group represented by the general formula (II) –Ar-A-$R^1$.

(II) Compounds of formula (I) wherein $X^2$ is a group represented by the general formula (II) –Ar-A-$R^1$.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

2. The claims are deemed to correspond to the species listed above in the following manner:

(I) Claims 1-4, 6-19 and 22-27 correspond to compounds of formula (I) wherein $X^1$ is a group represented by the general formula (II) –Ar-A-$R^1$.
(II) Claims 1-3, 5-21 and 23-27 correspond to compounds of formula (I) wherein $X^2$ is a group represented by the general formula (II) –Ar-A-$R^1$.

The following claim(s) are generic: claims 1-3, 6-19 and 23-27.

3. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The substituent on the steroidal ring system at positions 7- or 11- vary extensively and when taken as a whole result in vastly different compounds. Accordingly, unity of invention is lacking and restriction of the invention in accordance with the rules of unity of invention is proper.

4. During a telephone conversation with Mr. Sheridan Neimark on April 10, 2003 a provisional election was made with traverse to prosecute the species of example 3 found on page 339 of the present specification, i.e., compound of Group II, claims 1-3, 5-21 and 23-27. Affirmation of this election must be made by applicant in replying to this Office action. Based on the elected species, claims 3, 4, 9, 10, 14-17, 20, 22 and 23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### *Specification*

6. The abstract of the disclosure is objected to because of its length. Correction is required. See MPEP § 608.01(b).

7. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

### *Claim Rejections - 35 USC § 112*

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claim recites "wherein Ar, A and $R^1$ have the same meanings as defined above". Said variables are not defined in the instant claims and, thus, are not defined above as recited. It is suggested that the above-mentioned phrase be rewritten to read "wherein Ar, A and $R^1$ have the same meanings as defined in claim 1".

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 2, 5-7, 11-13, 18, 19 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Grunwell et al. ('621).

Grunwell et al. teach a generic group of 3-keto-7(α,β)-loweralkyl-5-ene steroids which can be isomerized to yield the corresponding 4-ene compounds having recognized biological properties (see the entire article, especially col. 1, line 63 – col. 2, line 44; col. 3, lines 60-70; col. 19, Example XII). The compound and composition taught by the reference are encompassed by the instant claims.

12. Claims 1, 2, 5, 7, 8, 11-13, 18, 19, 21 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Pierdet et al. ('413).

Pierdet et al. teach a generic group of compounds, such as 7α and 7β-(ω-carboxydecyl)-$\Delta^4$-androstene-17β-ol-3-one, useful as haptens and antigens (see the entire article, especially col. 1, line 24 – col. 2, line 58; col. 12, Example 5). The compounds and compositions taught by the reference are encompassed by the instant claims.

13. Claims 1, 2, 5-8, 11-13, 18, 19 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Labrie et al. ('375).

Labrie et al. teach 17β-hydroxy-7α-propyl-5α-androstan-3-one (see col. 8, lines 16-17). The compound and composition taught by the reference are encompassed by the instant claims.

### *Claim Rejections - 35 USC § 103*

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 1, 2, 5, 7, 8, 11-13, 18, 19 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grunwell et al. ('621).

Grunwell et al. teach a generic group of 3-keto-7(α,β)-loweralkyl-5-ene steroids which can be isomerized to yield the corresponding 4-ene compounds having recognized biological properties (see the entire article, especially col. 1, line 63 – col. 2, line 44; col. 3, lines 60-70; col. 19, Example XII).

The instant claims differ from the reference by reciting compounds not exemplified by Grunwell et al. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including that of the instant claims, because an ordinary artisan would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, would have biological properties.

16. Claims 1, 2, 5, 7, 8, 11-13, 18, 19, 21 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pierdet et al. ('413).

Pierdet et al. teach a generic group of compounds, such as 7α and 7β-(ω-carboxydecyl)-$\Delta^4$-androstene-17β-ol-3-one, useful as haptens and antigens (see the entire article, especially col. 1, line 24 – col. 2, line 58; col. 12, Example 5).

The instant claims differ from the reference by reciting compounds not exemplified by Pierdet et al. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including that of the instant claims, because an ordinary artisan would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole.

***Telephone Inquiry***

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
April 14, 2003